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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,095	10/04/2005	David Harry Fortune	2308/560	4198

7590 05/22/2009

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,095	FORTUNE ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-44,53 and 63-67* is/are pending in the application.

4a) Of the above claim(s) *8-11, 13-19, 22-23, 25-27, 31-44, 53, and 63-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 20-21, 24, and 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 1/28/2009 and 3/7/2009 have been entered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

No prior art against the elected species was found. The search was therefore expanded to nonelected embodiments, which is set forth in the prior art rejection below. The search was not extended to the entire scope of the claims since prior art was found for the generic claim. Claims 1-7, 20-21, 24, and 29-30 are currently under consideration. Claims 8-11, 13-19, 22-23, 25-27, 31-44, 53, and 63-67 are withdrawn as not reading on Applicant's elected species or that cited below by the Examiner to reject the claims.

Response to Arguments

Claim Rejections - 35 USC § 103

The rejection of claims 1-4, 6-7 and 29-30 under 35 U.S.C. 103(a) as being unpatentable over US 6989192 ('192) is maintained.

Applicant argues the following:

(1) A person of ordinary skill in the art would not consider looking at '192 for assistance in making the present invention. '192 refers to an improvement in standard polyacrylate pressure sensitive adhesives, which are known to the skilled person to have general industrial applicability and to be unsuitable for internal medical applications.

(2) '192 does not teach or suggest a naturally occurring or synthetic polymerisable and/or cross-linkable material *in particulate form and in admixture with a particulate material* comprising tissue-reactive functional groups as required by claim 1.

Applicant's arguments have been fully considered but are not found persuasive.

(1) In response to Applicant's argument that '192 is nonanalogous art, "a tissue-adhesive formulation" is being interpreted as an intended use of the formulation. The recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. That '192 does not appreciate the capacity of the composition to serve in internal medical applications does not negate the rejection. The formulation that is made obvious by '192 meets all the structural limitation of the instant claims, and is therefore capable of being used as a tissue-

adhesive formulation. ""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

(2) '192 states that organic solvents and/or water may be added to the polymerization reaction (see col 6, lines 19-20). Preferably, however, the process uses as little solvent as possible (see col 6, lines 23-24). Applicant argues that the solvent is not required for subsequent processing steps, but is essential in the polymerization reaction. The Examiner disagrees with Applicant's interpretation of the text. Nowhere does '192 state that solvent is essential to the polymerization, but that it is an optional component. Although the examples use solvent, the overall teaching clearly suggests that using as little solvent as possible is desirable. It would therefore be obvious to perform the polymerization in the absence of solvent (i.e. a dry mixture). Or if solvent is required, it would be obvious to start at low amounts of solvent to promote polymerization, in other words, as close to a dry mixture as possible. In either case, one would avoid adding solutions of component (a) with component (b).

It would be obvious to mix particles, in the absence or near-absence of solvent, of (a) acrylic acid and methacrylic acid derivatives with particles of (b) vinyl, acrylic and/or methacrylic monomers having a group X" (see col 5, lines 21-34). In this way,

there would desirably be no solvent present in the subsequent melt (see col 5, lines 35-36; col 6, lines 23-24).

New Grounds of Rejection

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 recites "wherein the formulation contains one material comprising tissue-reactive functional groups". Claim 1, from which claim 6 depends, recites "in admixture with particulate material comprising tissue-reactive functional groups" and the claim therefore already contains one material comprising tissue-reactive functional groups. Thus, claim 6 fails to further limit claim 1.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 20-21, 24, and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "a tissue-adhesive formulation comprising a naturally occurring or synthetic polymerisable and/or cross-linkable material in particulate form, the polymerisable and/or crosslinkable material being in admixture with particulate material comprising tissue-reactive functional groups." The group "a naturally occurring or synthetic polymerisable and/or cross-linkable material in particulate form" constitutes a large genus of compounds. This genus encompasses any material, of any chemical composition, which comprises two or more functional groups such as diacids, diols, diamines, etc, any material which comprises a carbon-carbon unsaturation, a host of biomolecules such as simple and complex sugars, amino acids, proteins, nucleotides, lipids, etc. The group "a material comprising tissue-reactive functional groups" constitutes a large genus of compounds. This genus encompasses any material, of any chemical composition, that contains at least one tissue-reactive functional group such as imido esters, p-nitrophenyl carbonates, N-hydroxysuccinimide esters, epoxides, isocyanates, acrylates, vinyl sulfones, orthopyridyl-disulfides, maleimides, aldehydes, iodoacetamides, etc. As both the first term and the second term above correspond to large genera, the combination of the first term, vis-à-vis, with the second term, encompasses a myriad of compound combinations. While the specification supports the scope of "a naturally occurring or synthetic polymerisable and/or cross-linkable material in particulate form", it does not support the scope of the combination, vis-à-vis, with "a material comprising tissue-reactive functional groups". The specification only describes NHS-activated PVP-co-

PAA with porcine albumin and NHS-activated PVP-co-PAA with human serum albumin. These two examples fail to represent the myriad of compound combinations encompassed by the instant claim. Thus, the skilled practitioner would not believe that Applicant had possession of the scope of the compound combinations, i.e. "a naturally occurring or synthetic polymerisable and/or cross-linkable material in particulate form" vis-à-vis "a material comprising tissue-reactive functional groups", at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-7, 24, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 20020106409 ('409). '409 discloses a tissue-adhesive formulation comprising poly(ethylene glycol) amine (a synthetic polymerisable or cross-linkable material) in particulate form in dry admixture with particles of poly(ethylene glycol) extended with succinimidyl glutarate ester (a particulate material comprising tissue-reactive functional groups) (see Example 1; paragraph 35). The poly(ethylene glycol)

extended with succinimidyl glutarate ester may be made by reacting a polymer precursor with N-hydroxysuccinimide (see paragraph 37). Other additives may include structural polymers such as human thrombin (see paragraph 50; Example 1). The addition of human thrombin serves as a second material comprising tissue-reactive functional groups, and therefore meets the requirement of instant claim 7.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

May 20, 2009